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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/642,522

08/15/2003

Joseph P. Errico

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11/01/2006

EXAMINER

PELLEGRINO, BRIAN E

SPINE MP

LERNER, DAVID, et al.

600 SOUTH AVENUE WEST

WESTFIELD, NJ 07090

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/642,522

Applicant(s)

ERRICO ET AL.

Examiner

Brian E. Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/14/06 has been entered.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the written disclosure failed to describe the "central region of the contact element being *unencumbered* by the coating".

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,9 are rejected under 35 U.S.C. 102(b) as being anticipated by Ralph et al. (5989291). Fig. 4 shows a intervertebral disc implant with first and second baseplates **100a,100b** with outward surfaces extending down and upward respectively that have grooves in a side outward surface with a vertebral contact element **120**

secured thereto. It can be seen that the central portion of the contact element **120** is remote from the outward surfaces so as to form a gap in the central area. Ralph also discloses an osteoconductive feature in the form of a coating adjacent to the element in the groove, col. 5, lines 59-61.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frey et al. (4932969) in view of Krebs et al. (5926685). Fig. 1 shows an artificial intervertebral disc with first and second baseplates **4,5** having domed outward facing surfaces. Frey et al. disclose the baseplates are formed of multiple layers, col. 2, lines 39-45. The examiner is interpreting the claimed elements "contact element of a wire mesh" in this way: since there are multiple layers the outer layer can be considered a domed mesh or contact element and an inner layer a baseplate. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054, 1055. The mesh is fully capable of having a convexity depth or footprint approximating the depth of a concave surface in a vertebrae. Frey does disclose the prosthesis is compressible (col. 1, lines 51-53), which can be interpreted that the baseplates are movable relative to one another. However, Frey et al. fail to disclose the outer surface has a coating. Krebs et al. teach that a coating or binder is used to secure

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a metal mesh to the surface of the implant, col. 2, lines 14,17,36-39. It would have been obvious to one of ordinary skill in the art to use the coating as taught by Krebs et al. with the implant of Frey et al. such that it provides a more secure mesh to the implant surface and eliminates any sliding of the baseplates. Since the coating is only used to bond a surface of the mesh to the surface of the implant body, the "contact element" would be unencumbered (as best understood).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baumgartner (5370697) in view of Hedman et al. (4759769). Fig. 5 shows a vertebral contact element **44** having a resting shape of a dome convexly extending from an orthopedic device **2**. Baumgartner discloses the contact element is a wire mesh (col. 3, lines 54-57) that is porous. The mesh is fully capable of having a convexity depth or footprint approximating the depth of a concave surface in a vertebrae. However, Baumgartner fails to disclose the outer surface having a groove or an osteoconductive feature, such as a coating adjacent the contact element. Hedman et al. teach (Figs. 1,2) that a recess or groove **34,52** is used in the plate surfaces to secure or retain the resilient spring elements therein. Hedman also teaches that a coating for osteoconductive purposes is placed on the baseplate surfaces, col. 4, lines 4-9. It would have been obvious to one of ordinary skill in the art to utilize a groove to retain a compressible member therein as taught by Hedman et al. with the implant of Baumgartner such that it provides a more secure fastening of the mesh to the implant surface and eliminates any sliding or dislodgement of the mesh from the baseplates. In addition it would have been obvious to one of ordinary skill in the art to incorporate a

coating as taught by Hedman with the vertebral implant of Baumgartner such that it provides a means to bond the surface with the vertebrae.

Claims 21-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baumgartner '697 in view of Krebs et al. '685. Baumgartner is explained supra. However, Baumgartner fails to disclose a coating disposed on an outer surface over the vertebral contact element. Krebs et al. is explained above. It would have been obvious to one of ordinary skill in the art to utilize a coating as taught by Krebs et al. for securing a mesh to the surface in the Baumgartner implant such that it prevents the mesh from dislodged from the outer surface under spinal loads or while inserting the implant.

Response to Arguments

Applicant's arguments filed 8/14/06 have been fully considered but they are not persuasive. In response to applicant's argument that the Ralph '291 reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the vertebral body contact element contacts the vertebrae and that it promotes bone ingrowth) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Claim 9 only required an adjacent osteoconductive feature of which the coating of the Ralph '291 device is clearly near the vertebral element in the groove.

Applicant argues the rejection over Frey in view of Krebs is not clear with respect to what the Examiner is interpreting as baseplates. As mentioned above, since Frey

discloses multiple layers, the outer layer is the contact element and the inner layer can be construed as a baseplate.

In response to applicant's arguments against the Baumgartner and Hedman references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant has misinterpreted the Examiner's rejection, the claim requires an outward surface groove including the contact element. Baumgartner disclosed the contact element on the outward surface and was lacking a groove in that surface. The Examiner took the teaching of Hedman that grooves can be in a surface to retain a compressible member at the location. Thus, the modification is to incorporate a groove in Baumgartner's outward surface just to retain the mesh thereon.

Since Applicant failed to discuss how the claims avoid the Baumgartner and Krebs references applied against the claims or distinguish from them, this rejection is maintained.

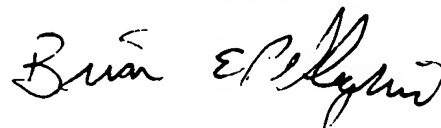
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Thursday from 7:30am to 5pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "Brian E. Pellegrino", is written over the printed name and title.